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10/521,628	09/08/2005	Neville Boden	5585-70293-01	2023
24197	7590	06/27/2007	EXAMINER	
KLARQUIST SPARKMAN, LLP			HA, JULIE	
121 SW SALMON STREET			ART UNIT	PAPER NUMBER
SUITE 1600			1654	
PORTLAND, OR 97204			MAIL DATE	DELIVERY MODE
			06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/521,628	BODEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 May 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3,38 and 96 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____                          |

**Continuation of Disposition of Claims:** Claims pending in the application are 1-13,17,19-21,23,24,28,29,36-38,41-58,61,63,69,71-73,76,81 and 96.

**Continuation of Disposition of Claims:** Claims withdrawn from consideration are 2-13,17,19-21,23,24,28,29,36,37,41-58,61,63,69,71-73,76 and 81.

## DETAILED ACTION

Response to Election/Restriction filed on May 29, 2007 is acknowledged. Claims 1-13, 17, 19-21, 23-24, 28-29, 36-38, 41-58, 61, 63, 69, 71-73, 76, 81 and 96 are pending in this application.

### *Restriction*

1. Applicant's election with traverse of Group I (claims 2, 8, 61 and 63 with the linking claims 1, 3-7, 9-10, 12, 19, 23-24, 36, 38, 41-58, 71-73, 76, 81 and 96) drawn to a peptide material comprising ribbons or fibrils/fibres in beta-sheet tape-like structure, antiparallel conformation of P11-1 peptide and the first method drawn to a method of tissue engineering in the reply filed on May 29, 2007 is acknowledged. The traversal is on the ground(s) that the peptide disclosed in Mihara et al (US 2003/0162696) does not disclose the specific claimed class of peptides restricted to a net +/- 2 charge at pH 7.5. This is not found persuasive because the inventions restricted are patentably distinct. Aggeli et al (Nature, 1997, 386: 259-262) discloses peptide sequence of P11-2 (QQRFQWWQFEQQ) and the proposed antiparallel beta-sheet arrangement of two molecules of the de novo peptide DN1 that indicates +2 and -2 net charge at neutral pH (see p. 261, left column, 2<sup>nd</sup> paragraph, and Figure 4). Additionally, the peptides claimed share only the core sequence "QQ". Four out of the 7 peptides share the core sequence "QQR"; three of the 7 peptides share the core sequence "QQRF"; two of the 7 peptides share the core sequence "QQOF". This requires independent searches. The search for each of the inventions is not co-extensive particularly with regard to the literature

Art Unit: 1654

search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper.

The requirement is still deemed proper and is therefore made FINAL. Search was conducted on the elected invention, peptide P11-1. This appears to be free of the prior art. Search was further extended to the broad claim 1. A prior art was found on this invention. Claim 2 is withdrawn from further consideration, since claim 2 recites P11-2 to P11-6 and P10-7 along with peptide P11-1, which is deemed free of prior art. Thus, claims 2, 4-13, 17, 19-21, 23-24, 28-29, 36-37, 41-58, 61, 63, 69, 71-73, 76, and 81 are withdrawn from further consideration. Claims 1, 3, 38 and 96 of the linking claims are examined on the merits in this office action.

### ***Objection-Specification***

2. The specification is objected to because of the following informalities: The arrangement of the specification is not outlined as below.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. The specification is objected to because of the following informalities: The title of Example 3 recites "A Rationally-Designed Self-Assembling Peptide P11-4...". However, Example 3 provides description on P11-5 (see paragraphs [0014]-[0016]). Additionally, Example 3 refers back to the incorrect example numbers. P11-3 is described in example 2 not example 1; P11-5 is described in example 3 not example 2 (see paragraph [0015]).

***Rejection-35 U.S.C. 112, 2<sup>nd</sup>***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites "wherein each peptide or pair of complimentary peptides comprises a net -2 or a +2 charge when in solution at physiological pH". This statement is unclear. For example, when looking at peptide P11-1 (QQRQQQQEQQQ), there is a +1 and -1 charges each from R and E, respectively. This would give a "net" charge of "0". If from each peptide, there is a net charge of "0". If a pair of complimentary peptides is involved, it would still give +2 and -2 charges each, and this leads to net charge of "0". So it is unclear as how the "net charge" is acquired, i.e., if the net charge is the final charge acquired at when the network of ribbons, fibrils or fibres are formed or if each individual peptide or pair of peptides give the "net charge".

***Rejection-35 U.S.C. 112, 1<sup>st</sup>***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3, 38 and 96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Art Unit: 1654

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

9. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient."

MPEP 2163.

10. Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480

Art Unit: 1654

F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

11. The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

12. In the instant case, the claims are drawn to a material comprising ribbons, fibrils or fibres having an antiparallel arrangement of peptides in a beta-sheet tape-like substructure. The generic statements material comprising ribbons, fibrils or fibres in a beta-sheet tape-like substructure does not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

Art Unit: 1654

13. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide or a peptide-like molecule that can form ribbons, fibrils or fibres in an antiparallel arrangement. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as a peptide or a peptide-like molecule or other peptidic molecules that can form antiparallel arrangements in a beta-sheet tape-like substructure.

14. The specification is limited to the peptide or peptide-like molecules that have 1 to 3 charged amino acids per 11 amino acids (see paragraph [0014]). The examples disclosed are peptides P11-1, P11-2, P11-3, P11-4, P11-5, P11-6 and an 10mer P10-7. The working example describes the peptide P11-3 in 145 mM NaCl, pH 7.5, self-

Art Unit: 1654

assembling into twisted beta-sheet fibrils (see Example 2); peptide P11-5 in 145 mM NaCl, pH 7.5, self-assembling into twisted beta-sheet fibrils (see Example 3). The working example only describes P11-1, P11-2, P11-3, P11-4, P11-5, P11-6 and P10-7 (see Examples 2-10). The specification does not describe any other peptides or any other type of peptide or peptide-like molecule that can form an antiparallel arrangement of peptides in a beta-sheet tape-like substructure. Descriptions of P11-1, P11-2, P11-3, P11-4, P11-5, P11-6 and P10-7 are not sufficient to encompass numerous other peptides that belong to the same genus. For example, there are five charged amino acids (D, E, H, K and R) and there are multiple polar/neutral amino acids. Additionally, there are non-natural amino acids, such as D-amino acids or beta-amino acids, which have charged functional groups and have polar/neutral functionality. Additionally, there are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up the genus. Additionally, the longer peptides having certain amino acids positioned in certain positions that can have the same antiparallel arrangement (for example, Lys $\beta$ -21 peptide). There are 20 naturally occurring amino acids that can be utilized in a sequence to have the same functional characteristics as the claimed peptides. Since innumerable peptide possibilities can be utilized, there is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

15. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

***Rejection-35 U.S.C. 102***

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1, 3, 38 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Aggeli et al (Biomacromolecules, 2001, 2: 378-388).

18. The instant claims are drawn to a material comprising ribbons, fibrils or fibres, wherein each of the ribbons, fibrils or fibres have an antiparallel arrangement of peptides in a beta-sheet tape-like substructure having a net -2 or a +2 charge when in solution at physiological pH. Furthermore, the claims are drawn to a self assembling peptide (SAP), wherein the SAP forms a tape in an aqueous medium and is made up of 3 or more polar/neutral amino acids and a plurality of charged amino acids.

Art Unit: 1654

19. Aggeli et al teach that an oligomeric peptides can be designed which undergo one-dimensional self-assembly in solution to form beta-sheet tapes (see abstract). Furthermore, the reference teaches a 24-residue peptide, K24 (KLEALVYVLGFFTLGIMLSYIR) that form beta-sheet tape and the tapes behave like semiflexible chains with persistence lengths of several hundred nanometers and much longer contour lengths (see abstract, 1<sup>st</sup> paragraph of Introduction, and p. 378, right column, 2<sup>nd</sup> paragraph). K24 peptide consists of 2 positively charged amino acids (K and R) and one negatively charged amino acid (E). Thus the net charge of a monomer would be +1. The reference further discloses that the polymers of K24 are thus believed to be intermolecular beta-sheet tapes produced by one-dimensional association of peptides. Since more than one peptide is being utilized, there would be a net charge of at least a +2 when two K24 peptides self-assemble (see p. 379, left column, 1<sup>st</sup> paragraph). It is well known in the art that amino acids having + or – charged functional groups would have + or – charge at physiological pH. Thus, this reads on claims 1, 3 and 38. The reference further teaches that the properties of the tapes, their long contour and persistence lengths and the opportunity of lateral tape-tape attraction as well as topological entanglements, are probably responsible for stabilizing a tape network with unusually large mesh size already at low peptide concentrations...the network of entangled tapes approximate in its behavior that of semirigid polymers (see p. 387, right column, 1<sup>st</sup> paragraph). This reads on claims 1, 3, 38 and 96.

***Conclusion***

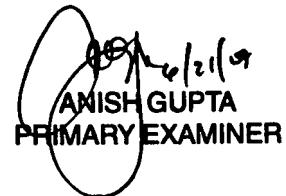
20. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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